

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)
CALIFORNIA, COLORADO,)
CONNECTICUT, DELAWARE, DISTRICT)
OF COLUMBIA, FLORIDA, GEORGIA,)
HAWAII, ILLINOIS, INDIANA, IOWA,)
LOUISIANA, MARYLAND,)
MASSACHUSETTS, MICHIGAN,)
MINNESOTA, MONTANA, NEVADA, NEW)
JERSEY, NEW MEXICO, NEW YORK,)
NORTH CAROLINA, OKLAHOMA, RHODE)
ISLAND, TENNESSEE, TEXAS, VIRGINIA,)
WISCONSIN)

Case No. 5:15-cv-6264-EGS

Ex rel. CATHLEEN FORNEY)

Plaintiffs,)

vs.)

MEDTRONIC, INC.,)

Defendant.)

**DEFENDANT MEDTRONIC, INC.'S ANSWER TO
THE SECOND AMENDED COMPLAINT**

Medtronic, Inc. (Medtronic or Defendant), through its attorneys, hereby answers the Second Amended Complaint (SAC) in the above-captioned matter. Medtronic incorporates the headings of the SAC solely for organizational and reference purposes. Medtronic denies any allegations contained in the headings, tables, and unnumbered paragraphs of the SAC, as well as any characterizations of the documents referred to in the SAC. Every allegation that is not specifically admitted is hereby denied.

1. Medtronic states that it or its subsidiaries manufactures and sells medical devices, including medical devices used during heart surgeries and procedures, including pacemakers,

defibrillators, stents and catheters. The remainder of Paragraph 1 states legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the remaining allegations in Paragraph 1.

2. The allegations in Paragraph 2 state legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 2.

3. Medtronic states that Relator brought this action on behalf of the United States and the Plaintiff States named in the Second Amended Complaint, and that all have declined to intervene in this action.

PARTIES

4. Medtronic states that Relator's employment at Medtronic began in 1996 and ended in 2012. Medtronic lacks knowledge or information sufficient to form a belief as to Relator's residence. Medtronic denies that it retaliated against Relator and it denies the remaining allegations in Paragraph 4.

5. Paragraph 5 states legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 5.

6. Medtronic states that Relator brought this action on behalf of the United States and the Plaintiff States named in the Second Amended Complaint, and that all have declined to intervene in this action. Medtronic further states that it lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 6.

7. Paragraph 7 states legal conclusions to which no response is required. The statute referenced in Paragraph 7 speaks for itself, and Medtronic denies any characterizations of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 7.

8. Paragraph 8 states legal conclusions to which no response is required. The statutes referenced in Paragraph 8 speak for themselves, and Medtronic denies any characterizations of them. Medtronic states that Relator brought this action on behalf of the Plaintiff States named in the Second Amended Complaint, and that all have declined to intervene in this action. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 8.

9. Defendant states that Medtronic, Inc. is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota. Defendant further states that Medtronic, Inc.'s parent corporation, Medtronic plc, is a public limited company organized under the laws of Ireland. Defendant states that its website speaks for itself, and Defendant denies any characterization thereof. Defendant further states its annual revenue is available in public securities filings that speak for themselves.

JURISDICTION AND VENUE

10. Paragraph 10 states legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 10.

11. Paragraph 11 states legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 11.

FACTUAL ALLEGATIONS

12. Medtronic states that Relator was previously employed as a District Service Manager reporting to the District Manager for the Eastern Pennsylvania District. Medtronic denies the remaining allegations in Paragraph 12.

13. Medtronic admits the allegation in Paragraph 13.

14. Medtronic states that it markets and promotes the purchase of its devices nationwide. Medtronic's filings with the Securities and Exchange Commission are publicly available and

speak for themselves, and Medtronic denies any characterization thereof. Medtronic denies the remaining allegations in Paragraph 14.

15. Medtronic admits that it marketed the products described in Paragraph 15, but it denies that all of the listed products are stand-alone devices that are implanted into patients. Some of the listed products are features available on, or reports that can be generated from, certain devices, and are not implantable devices themselves.

16. Medtronic states that its employees engaged in strategic planning, gathered data on customers, and marketed to customers. Medtronic denies the remaining allegations in Paragraph 16.

17. The document referenced in Paragraph 17 speaks for itself, and Medtronic denies any characterization of it. Medtronic further denies the remaining allegations in Paragraph 17.

18. The document referenced in Paragraph 18 speaks for itself, and Medtronic denies any characterization of it. Medtronic further denies the remaining allegations in Paragraph 18.

19. The allegations in Paragraph 19 contain legal conclusions to which no response is required. The document quoted in Paragraph 19 speaks for itself, and Medtronic denies any characterization of it. Medtronic admits that it employed clinical specialists and device check specialists nationwide, but denies the remaining allegations in Paragraph 19.

20. The document quoted in Paragraph 20 speaks for itself, and Medtronic denies any characterization of it. Medtronic denies the remaining allegations in Paragraph 20 in the form and manner alleged.

21. Paragraph 21 contains legal conclusions to which no response is required. To the extent that paragraph 21 is based on or recites information from documents, the documents speak for themselves. Medtronic admits that it used a computer-based system called Device and

Registrant Tracking. Medtronic denies the remaining allegations in Paragraph 21 in the form and manner alleged.

22. Medtronic admits the allegations in Paragraph 22.

23. The allegations in Paragraph 23 contain legal conclusions to which no response is required. The documents referenced in Paragraph 23 speak for themselves, and Medtronic denies any characterization of them. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 23.

24. Paragraph 24 contains legal conclusions to which no response is required. The document referenced in Paragraph 24 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 24.

25. The document referenced in Paragraph 25 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 25.

26. Paragraph 26 contains legal conclusions to which no response is required. The document referenced and quoted in Paragraph 26 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 26.

27. The document referenced in Paragraph 27 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 27.

28. The document referenced in Paragraph 28 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 28.

29. Paragraph 29 contains legal conclusions to which no response is required. To the extent that paragraph 29 is based on or recites information from documents, the documents speak for themselves. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 29.

30. The document referenced in Paragraph 30 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 30.

31. Paragraph 31 contains legal conclusions to which no response is required. The contracts referenced in Paragraph 31 speak for themselves, and Medtronic denies any characterization of them. Medtronic denies the remaining allegations in Paragraph 31 in the form and manner alleged.

32. Paragraph 32 contains legal conclusions to which no response is required. The document referenced in Paragraph 32 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 32.

33. Paragraph 33 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 33.

34. The document referenced in Paragraph 34 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the remaining allegations in Paragraph 34 in the form and manner alleged.

35. Medtronic lacks information or knowledge sufficient to form a belief as to the truth of the academic research findings referenced in Paragraph 35. Paragraph 35 also contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 35.

36. Paragraph 36 contains legal conclusions to which no response is required. The documents referenced in Paragraph 36 speak for themselves, and Medtronic denies any characterization of them. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 36.

37. Paragraph 37 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 37 in the form and manner alleged.

38. The document apparently referenced in Paragraph 38 speaks for itself, and Medtronic denies any characterization of it.

39. Paragraph 39 contains legal conclusions to which no response is required. The document referenced in Paragraph 39 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 39.

40. Paragraph 40 contains legal conclusions to which no response is required. The documents referenced in Paragraph 40 speak for themselves, and Medtronic denies any characterization of them. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 40.

41. Paragraph 42 contains legal conclusions to which no response is required. The documents referenced in Paragraph 42 speak for themselves, and Medtronic denies any characterization of them. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 42.

42. Medtronic admits that it is aware that claims for payment for Medicare, Medicaid and certain other federal healthcare programs are submitted on CMS Form 1500.

43. Paragraph 43 contains legal conclusions to which no response is required. To the extent that a further response is required, Medtronic denies the allegations in Paragraph 43.

44. The document referenced in Paragraph 44 speaks for itself, and Medtronic denies any characterization of it.

45. The document referenced in Paragraph 45 speaks for itself, and Medtronic denies any characterization of it.

46. Medtronic admits that it belongs to AdvaMed, the trade association for the medical device industry. The document referenced in Paragraph 46 speaks for itself, and Medtronic denies any characterization of it.

47. Paragraph 47 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 47.

48. Paragraph 48 contains legal conclusions to which no response is required. The document referenced in Paragraph 48 speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 48.

49. Paragraph 49 contains legal conclusions to which no response is required. Medtronic lacks knowledge or information sufficient to form a belief as to whether the patients identified by their initials in this chart underwent the procedures identified on the dates and locations alleged in the table appended to Paragraph 49. To the extent that any further response is required, Medtronic denies the remaining allegations in Paragraph 49 and the table it contains.

50. Paragraph 50 contains legal conclusions to which no response is required. Medtronic lacks knowledge or information sufficient to form a belief as to the number of patients treated on specific days in the specific cities referenced in Paragraph 50 and the unnumbered paragraphs

that follow it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 50 and the unnumbered paragraphs that follow it.

51. Paragraph 51 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the remaining allegations in Paragraph 51.

52. The documents referenced in Paragraph 52 speak for themselves, and Medtronic denies any characterization of them. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 52 and the unnumbered paragraphs that follow it.

53. Medtronic admits that Medicare pays for many cardiac treatments, but Medtronic denies the vague and ambiguous manner in which this allegation is worded in Paragraph 53. Additionally, Paragraph 53 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the remaining allegations in Paragraph 53.

54. Paragraph 54 contains legal conclusions to which no response is required. Medtronic admits that employees in the Cardiac Rhythm Disease Management business unit used software to assist with calendaring and coverage, including at certain times Salesforce software. The documents referenced in Paragraph 54 speak for themselves, and Medtronic denies any characterization of them. To the extent that any further response is required, Medtronic denies the remaining allegations in Paragraph 54.

55. Paragraph 55 contains legal conclusions to which no response is required. The filing with the Securities and Exchange Commission referenced in Paragraph 55 is publicly available and speaks for itself, and Medtronic denies any characterization of it. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 55.

COUNT ONE – FALSE CLAIMS

56. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-55, above.

57. Paragraph 57 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 57.

58. Paragraph 58 contains legal conclusions to which no response is required. Medtronic admits that this action was initially filed under seal, and that Relator has filed a certificate of service attesting that the Second Amended Complaint was served on the United States. Medtronic currently lacks knowledge or information sufficient to form a belief as to whether Relator served on the United States a written disclosure or related material evidence and information.

59. Paragraph 59 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 59.

60. Paragraph 60 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 60.

61. Paragraph 61 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 61.

COUNT TWO – VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)

62. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-61, above.

63. The statutory provisions quoted in Paragraph 63 speak for themselves, and Medtronic denies any characterizations of them.

64. Paragraph 64 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 64.

65. Paragraph 65 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 65.

COUNT THREE – VIOLATIONS OF THE COLORADO MEDICAID FCA
Col. Rev. Stat. § 25.5-4-305

66. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-65, above.

67. The statutory provisions quoted in Paragraph 67 speak for themselves, and Medtronic denies any characterizations of them.

68. Paragraph 68 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 68.

69. Paragraph 69 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 69.

COUNT FOUR – VIOLATIONS OF THE CONNECTICUT FCA FOR MEDICAL ASSISTANCE PROGRAMS
Conn. Gen. Stat. § 17b-301b

70. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-69, above.

71. The statutory provisions quoted in Paragraph 71 speak for themselves, and Medtronic denies any characterizations of them.

72. Paragraph 72 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 72.

73. Paragraph 73 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 73.

COUNT FIVE – VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6. § 1201(a)

74. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-73, above.

75. The statutory provisions quoted in Paragraph 75 speak for themselves, and Medtronic denies any characterizations of them.

76. Paragraph 76 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 76.

77. Paragraph 77 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 77.

COUNT SIX – VIOLATIONS OF THE DISTRICT OF COLUMBIA FCA
D.C. Code § 2-2308.14(a)

78. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-77, above.

79. The statutory provisions quoted in Paragraph 79 speak for themselves, and Medtronic denies any characterizations of them.

80. Paragraph 80 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 80.

81. Paragraph 81 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 81.

COUNT SEVEN – VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)

82. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-81, above.

83. The statutory provisions quoted in Paragraph 83 speak for themselves, and Medtronic denies any characterizations of them.

84. Paragraph 84 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 84.

85. Paragraph 85 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 85.

**COUNT EIGHT – VIOLATIONS OF THE GEORGIA STATE FALSE MEDICAID
CLAIMS ACT**

Ga. Code Ann. § 49-4-168.1

86. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-85, above.

87. The statutory provisions quoted in Paragraph 87 speak for themselves, and Medtronic denies any characterizations of them.

88. Paragraph 88 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 88.

89. Paragraph 89 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 89.

COUNT NINE – VIOLATIONS OF THE HAWAII FCA

Haw. Rev. Stat. § 661-21

90. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-89, above.

91. The statutory provisions quoted in Paragraph 91 speak for themselves, and Medtronic denies any characterizations of them.

92. Paragraph 92 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 92.

93. Paragraph 93 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 93.

**COUNT TEN – VIOLATIONS OF THE ILLINOIS FALSE CLAIMS
WHISTLEBLOWER REWARD AND PROTECTION ACT**
740 Ill. Comp. Stat. § 175/3(a)

94. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-93, above.

95. The statutory provisions quoted in Paragraph 95 speak for themselves, and Medtronic denies any characterizations of them.

96. Paragraph 96 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 96.

97. Paragraph 97 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 97.

COUNT ELEVEN – VIOLATIONS OF THE IOWA FALSE CLAIMS ACT
Iowa Code § 15-5-685.2

98. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-97, above.

99. The statutory provisions quoted in Paragraph 99 speak for themselves, and Medtronic denies any characterizations of them.

100. Paragraph 100 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 100.

101. Paragraph 101 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 101.

**COUNT TWELVE – VIOLATIONS OF THE INDIANA FALSE CLAIMS AND
WHISTLEBLOWER PROTECTION ACT**
Ind. Code § 5-5.5-2

102. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-101, above.

103. The statutory provisions quoted in Paragraph 103 speak for themselves, and Medtronic denies any characterizations of them.

104. Paragraph 104 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 104.

105. Paragraph 105 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 105.

**COUNT THIRTEEN – VIOLATIONS OF THE LOUISIANA FCA/MEDICAL
ASSISTANCE PROGRAMS INTEGRITY LAW**
La. Rev. Stat. Ann. § 46:438.3

106. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-105, above.

107. The statutory provisions quoted in Paragraph 107 speak for themselves, and Medtronic denies any characterizations of them.

108. The statutory provisions quoted in Paragraph 108 speak for themselves, and Medtronic denies any characterizations of them.

109. The statutory provisions quoted in Paragraph 109 speak for themselves, and Medtronic denies any characterizations of them.

110. The statutory provisions quoted in Paragraph 110 speak for themselves, and Medtronic denies any characterizations of them.

111. Paragraph 111 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 111.

112. Paragraph 112 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 112.

**COUNT FOURTEEN – VIOLATIONS OF THE MARYLAND FALSE HEALTH
CLAIMS ACT**
Md. Code Ann., Health-Gen. § 2-602

113. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-112, above.

114. The statutory provisions quoted in Paragraph 114 speak for themselves, and Medtronic denies any characterizations of them.

115. Paragraph 115 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 115.

116. Paragraph 116 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 116.

COUNT FIFTEEN – VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws ch. 12, § 5B

117. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-116, above.

118. The statutory provisions quoted in Paragraph 118 speak for themselves, and Medtronic denies any characterizations of them.

119. Paragraph 119 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 119.

120. Paragraph 119 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 119.

COUNT SIXTEEN – VIOLATIONS OF THE MICHIGAN MEDICAID FCA
Mich. Comp. Laws § 400.601 et seq.

121. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-120, above.

122. The statutory provisions quoted in Paragraph 122 speak for themselves, and Medtronic denies any characterizations of them.

123. The statutory provisions quoted in Paragraph 123 speak for themselves, and Medtronic denies any characterizations of them.

124. The statutory provisions quoted in Paragraph 124 speak for themselves, and Medtronic denies any characterizations of them.

125. The statutory provisions quoted in Paragraph 125 speak for themselves, and Medtronic denies any characterizations of them.

126. The statutory provisions quoted in Paragraph 126 speak for themselves, and Medtronic denies any characterizations of them.

127. Paragraph 127 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 127.

COUNT SEVENTEEN – VIOLATIONS OF THE MINNESOTA FCA
Minn. Stat. § 15C.02(a)

128. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-127, above.

129. The statutory provisions quoted in Paragraph 129 speak for themselves, and Medtronic denies any characterizations of them.

130. Paragraph 130 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 130.

131. Paragraph 131 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 131.

COUNT EIGHTEEN – VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT
Mont. Code Ann. 17-8-401, et seq.

132. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-131, above.

133. Medtronic admits that Relator commenced this case on behalf of the state of Montana, and that Montana has declined to intervene in this action.

134. The statutory provisions quoted in Paragraph 134 speak for themselves, and Medtronic denies any characterizations of them.

135. Paragraph 135 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 135.

136. Paragraph 136 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 136.

COUNT NINETEEN – VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)

137. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-136, above.

138. The statutory provisions quoted in Paragraph 138 speak for themselves, and Medtronic denies any characterizations of them.

139. Paragraph 139 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 139.

140. Paragraph 140 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 140.

COUNT TWENTY – VIOLATIONS OF THE NEW JERSEY FCA
N.J. Stat. Ann. § 2A:32C-1

141. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-140, above.

142. The statutory provisions quoted in Paragraph 142 speak for themselves, and Medtronic denies any characterizations of them.

143. Paragraph 143 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 143.

144. Paragraph 144 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 144.

COUNT TWENTY-ONE – VIOLATIONS OF THE NEW MEXICO MEDICAID FCA
N.M. Stat. Ann. § 27-14-4

145. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-144, above.

146. The statutory provisions quoted in Paragraph 146 speak for themselves, and Medtronic denies any characterizations of them.

147. Paragraph 147 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 147.

148. Paragraph 148 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 148.

COUNT TWENTY-TWO – VIOLATIONS OF THE NEW YORK FCA
N.Y. State Fin. Law § 189

149. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-148, above.

150. The statutory provisions quoted in Paragraph 150 speak for themselves, and Medtronic denies any characterizations of them.

151. Paragraph 151 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 151.

152. Paragraph 152 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 152.

COUNT TWENTY-THREE – VIOLATIONS OF THE NORTH CAROLINA FCA
N.C. Gen. Stat. § 1-607(a)

153. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-153, above.

154. The statutory provisions quoted in Paragraph 154 speak for themselves, and Medtronic denies any characterizations of them.

155. Paragraph 155 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 155.

156. Paragraph 156 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 156.

COUNT TWENTY-FOUR – VIOLATIONS OF THE OKLAHOMA MEDICAID FCA
Okla. Stat. Ann. tit. 63 § 5053.1(B)

157. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-156, above.

158. The statutory provisions quoted in Paragraph 158 speak for themselves, and Medtronic denies any characterizations of them.

159. Paragraph 159 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 159.

160. Paragraph 160 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 160.

COUNT TWENTY-FIVE – VIOLATIONS OF RHODE ISLAND STATE FCA
R.I. Gen. Laws § 9-1.1-3(a)

161. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-160, above.

162. The statutory provisions quoted in Paragraph 162 speak for themselves, and Medtronic denies any characterizations of them.

163. Paragraph 163 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 163.

164. Paragraph 164 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 164.

**COUNT TWENTY-SIX – VIOLATIONS OF THE TENNESSEE MEDICAID FALSE
CLAIMS ACT**
Tenn. Code Ann. § 71 – 5-182 et seq.

165. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-164, above.

166. The statutory provisions referenced in Paragraph 166 speak for themselves, and Medtronic denies any characterizations of them.

167. Paragraph 167 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 167.

COUNT TWENTY-SEVEN – VIOLATIONS OF TEXAS FCA
Tex. FCA Hum. Res. Code § 32.039(b), (c)

168. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-167, above.

169. The statutory provisions quoted in Paragraph 169 speak for themselves, and Medtronic denies any characterizations of them.

170. Paragraph 170 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 170.

171. Paragraph 171 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 171.

**COUNT TWENTY-EIGHT– VIOLATIONS OF THE VIRGINIA FRAUD AGAINST
TAXPAYERS ACT**
Va. Code Ann. § 8.01-216.3(A)

172. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-171, above.

173. The statutory provisions quoted in Paragraph 173 speak for themselves, and Medtronic denies any characterizations of them.

174. Paragraph 174 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 174.

175. Paragraph 175 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 175.

**COUNT TWENTY-NINE – VIOLATIONS OF THE WISCONSIN FALSE CLAIMS FOR
MEDICAL ASSISTANCE LAW
Wis. Stat. Ann. § 20.931(2)**

176. Medtronic repeats and incorporates by reference its answers to Paragraphs 1-175, above.

177. The statutory provisions quoted in Paragraph 177 speak for themselves, and Medtronic denies any characterizations of them.

178. Paragraph 178 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 178.

179. Paragraph 179 contains legal conclusions to which no response is required. To the extent that any further response is required, Medtronic denies the allegations in Paragraph 179.

AFFIRMATIVE DEFENSES

Medtronic sets forth the following affirmative defenses. By asserting the defenses set forth below and herein, Defendants do not allege or admit that they have the burden of proof and/or the burden of persuasion with respect to any of these defenses, or that Relator is relieved of the burden to prove each and every element of her claims and the damages, if any, to which Relator claims to be entitled. Medtronic also states that it currently has insufficient knowledge or

information on which to form a belief as to whether it may have additional, as yet unstated, affirmative defenses available to it. Medtronic reserves the right to assert additional affirmative defenses in the event that discovery indicates that such defenses are available. Medtronic therefore reserves the right to amend this answer if necessary.

FIRST DEFENSE

Relator's Second Amended Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

The Second Amended Complaint and each purported cause of action set forth therein fails to comply with Federal Rule of Civil Procedure 9(b) in that the allegations are not stated with particularity.

THIRD DEFENSE

Relator's claims are barred, in whole or in part, to the extent that Relator lacks standing or capacity under the False Claims Act or the state-law analogs to bring the claims raised in this suit.

FOURTH DEFENSE

Relator's claims are barred, in whole or in part, to the extent that Relator has waived her right to bring the claims raised in this suit.

FIFTH DEFENSE

Relator's claims fail to allege Medtronic's intent sufficient to state a claim pursuant to the False Claims Act or state-law analogs, and Medtronic did not act "knowingly" in violation of the False Claims Act or the state-law analogs. Further, even if the actions alleged by Relator occurred, said actions were taken in good faith and not with any improper or illegal purpose, intent, or knowledge.

SIXTH DEFENSE

Relator's claims are barred, in whole or in part, because Defendant's conduct was in compliance with, or authorized by, laws and regulations administered by any regulatory body or officer acting under state or federal statutory authority.

SEVENTH DEFENSE

The damages alleged by Relator, if any, are the result of acts or omissions committed by third persons over whom Medtronic had neither control nor responsibility, and whose actions or inactions cannot be imputed to Medtronic.

EIGHTH DEFENSE

Insofar as Relator's claims alleged remuneration under the Anti-Kickback Statute, the alleged remuneration falls within a relevant "safe harbor" provision or regulations of that statute.

NINTH DEFENSE

The alleged conduct of Medtronic complained of in the Second Amended Complaint was not material to the payment of any alleged false or fraudulent claims.

TENTH DEFENSE

Any inaccurate or incorrect claims Defendants allegedly made or caused to be made were not material.

ELEVENTH DEFENSE

Because the penalties and treble damages authorized under the False Claims Act so exceed any actual loss incurred by the government as a result of any claims paid, such penalties and treble damages would violate the Excessive Fines Clause of the Eighth Amendment to the United States Constitution.

TWELFTH DEFENSE

An award of statutory or punitive damages would violate Defendants' rights to due process; Relator's claim for damages is therefore barred by the Constitutions of the United States and of the Plaintiff States.

THIRTEENTH DEFENSE

Relator's claims are barred because they rely upon ambiguous provisions of the False Claims Act, the Anti-Kickback Statute, and other provisions of law, and the rule of lenity requires such ambiguities to be construed in Defendant's favor.

FOURTEENTH DEFENSE

Relator's claims are barred, in whole or in part, because the conduct of employees alleged in the Second Amended Complaint cannot be imputed to Medtronic under the doctrine of respondeat superior.

FIFTEENTH DEFENSE

Relator's claims are barred, in whole or in part, because any alleged payments or remuneration at issue were at fair market value.

SIXTEENTH DEFENSE

Relator's claims are barred because Medtronic has not made, or caused to be made, any false claims.

SEVENTEENTH DEFENSE

Relator's claims are barred, in whole or in part, by the statute of limitations.

EIGHTEENTH DEFENSE

Relator's claims are barred, in whole or in part, by the doctrine of ratification.

NINETEENTH DEFENSE

Relator's claims are barred, in whole or in part, under the doctrine of laches.

TWENTIETH DEFENSE

Relator's claims are barred, in whole or in part, under the doctrine of in pari delicto, unclean hands, fraud, and/or by Relator's own improper conduct.

TWENTY-FIRST DEFENSE

Relator's claims are barred, in whole or in part, under the doctrine of release.

TWENTY-SECOND DEFENSE

Relator's claims are barred, in whole or in part, under the doctrine of waiver.

TWENTY-THIRD DEFENSE

Relator's claims are barred, in whole or in part, because the United States and Plaintiff States had actual or constructive knowledge of the relevant facts and therefore Relator's claims are not false or knowingly false and, alternatively, the United States and Plaintiff States were not defrauded.

TWENTY-FOURTH DEFENSE

Relator's claims are barred, in whole or in part, because the United States and Plaintiff States have not suffered an actual injury.

TWENTY-FIFTH DEFENSE

Relator's claims are barred, in whole or in part, because Medtronic's conduct was protected by the First Amendment.

Respectfully submitted,

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Date: August 28, 2017

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IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
CALIFORNIA, COLORADO,)	
CONNECTICUT, DELAWARE, DISTRICT)	
OF COLUMBIA, FLORIDA, GEORGIA,)	
HAWAII, ILLINOIS, INDIANA, IOWA,)	
LOUISIANA, MARYLAND,)	Case No. 5:15-cv-6264-EGS
MASSACHUSETTS, MICHIGAN,)	
MINNESOTA, MONTANA, NEVADA, NEW)	
JERSEY, NEW MEXICO, NEW YORK,)	
NORTH CAROLINA, OKLAHOMA, RHODE)	
ISLAND, TENNESSEE, TEXAS, VIRGINIA,)	
WISCONSIN)	
)	
<i>Ex rel.</i> CATHLEEN FORNEY)	
)	
Plaintiffs,)	
)	
vs.)	
)	
MEDTRONIC, INC.,)	
)	
Defendant.)	
)	

CERTIFICATE OF SERVICE

The foregoing document was filed electronically on August 28, 2017, and is available for viewing and downloading via the Eastern District of Pennsylvania's Electronic Case File (ECF) system. The foregoing document will be sent electronically via the ECF system to the registered participants as identified on the Notice of Electronic Filing. I certify that on August 28, 2017, in addition to the Notice of Electronic Filing automatically generated by the ECF system, I caused the foregoing document to be served via email upon the following recipients, including the Plaintiff

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